Remarks

The Office Action mailed May 10, 2011 has been received and reviewed. Claims 29, 31, 33-36, and 38 having been amended, claims 8 and 21-28 having been canceled herein, and no claims having been added herein, the pending claims are claims 29-38.

Independent claims 29 and 34 have been amended to recite a method for treating a mammal in and/or released from an intensive care unit (ICU), which is supported by the specification at, for example, page 3, line 27 to page 4, line 11 of WO 2005/067548 A2.

Claims 31 and 35 have been amended to recite that 1 to 20 grams of D-ribose is administered orally one to four times daily, which is supported by the specification at, for example, page 3, lines 22-23 and page 4, lines 8-10 of WO 2005/067548 A2.

Claims 33 and 36 have been amended to recite that 30 to 300 mg/kg/hour of pyrogen-free D-Ribose is administered intravenously, which is supported by the specification at, for example, page 3, lines 15, 19, and 30-31; and page 4, line 4 of WO 2005/067548 A2.

Claim 38 has been amended to recite a composition comprising 5% to 30% w/v pyrogen-free D- Ribose and 5% to 30% w/v D-Glucose, which is supported by the specification at, for example, page 3, lines 15-18; and page 3, line 31 to page 4, line 2 of WO 2005/067548 A2.

Reconsideration and withdrawal of the rejections are respectfully requested.

Rejection under 35 U.S.C. §112, First Paragraph

The Examiner rejected claims 21-38 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 21-28 having been canceled, Applicants respectfully traverse this rejection as applied to claims 29-38 (as amended).

First, the Examiner alleged that the present specification lacks support for the recited dosage forms, dosages, and routes of administration for administration of ribose to a mammal having sepsis. Applicants disagree. Independent claims 29 and 34 (as amended) each recite a method for treating sepsis in a mammal in and/or released from an intensive care unit (ICU). The dosage forms, dosages, and routes of administration for administration of ribose to a

mammal in and/or released from an intensive care unit (ICU) recited in claims 29-38 (as amended) are explicitly supported by the specification, for example, as discussed in the "Remarks" section herein above. The specification further recites that "a common condition requiring ICU admittance is sepsis" (page 24, line 9 of WO 2005/067548 A2). Thus, for at least this reason, Applicants respectfully submit that the dosage forms, dosages, and routes of administration recited in claims 29-38 (as amended) for treating sepsis by the administration of ribose to a mammal in and/or released from an intensive care unit (ICU) are adequately supported by the specification to satisfy the written description requirement of 35 U.S.C. §112, first paragraph.

Second, the Examiner alleged that the present specification lacks support for concurrent treatment with antibiotic and ribose. Applicants disagree. The specification clearly discloses the commonly known antibiotic therapy for the treatment of sepsis (e.g., page 24, line 15 of WO 2005/067548 A2). Further, the present specification further discloses ***ribose administration as an adjunct*** to the usual therapies for sepsis (e.g., page 24, lines 22-23). For at least this reason, Applicants respectfully submit that concurrent treatment with antibiotic (i.e., a usual therapy for sepsis) and the adjunct ribose is adequately supported by the specification to satisfy the written description requirement of 35 U.S.C. §112, first paragraph.

Reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph, are respectfully requested.

Rejection under 35 U.S.C. §102(b)

The Examiner rejected claims 8, 21-22, and 25-26 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,159,942 (St. Cyr '942). Claims 8, 21-22, and 25-26 having been canceled, Applicants respectfully submit that this rejection has been rendered moot.

Reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b) are respectfully requested.

Rejections under 35 U.S.C. §103(a)

The Examiner rejected claims 23-28 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,159,942 (St. Cyr '942) in view of U.S. Patent No. 6,218,366 (St. Cyr '366) and Taylor et al. (*Am. J. Physiol. Lung Cell Mol. Physiol.*, 1998; *275*:L139-L144). Claims 23-28 having been canceled, Applicants respectfully submit that this rejection has been rendered moot.

The Examiner rejected claims 29-38 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,159,942 (St. Cyr '942) in view of Cunha (*Med. Clin. North Am.*, 1995 May; *79*(3):551-558, abstract only); or over U.S. Patent No. 6,159,942 (St. Cyr '942) in view of U.S. Patent No. 6,218,366 (St. Cyr '366) and Taylor et al. (*Am. J. Physiol. Lung Cell Mol. Physiol.*, 1998; *275*:L139-L144) as applied to claims 23-28, and further in view of Cunha (*Med. Clin. North Am.*, 1995 May; *79*(3):551-558, abstract only). Applicants respectfully traverse these rejections of claims 29-38 (as amended).

St. Cyr '942 "relates to compositions and methods for increasing the energy available to mammals having reduced energy availability or expending high levels of energy" (column 1, lines 9-12 of St. Cyr '942). "[A] pentose such as D-ribose is given orally before, during and after a period of high ATP demand, in amounts effective to enhance the energy of the mammal. Mammals given ribose are able to exercise longer, to achieve a higher intensity and subjectively have more energy than those not given ribose" (column 3, lines 15-20 of St. Cyr '942). Although St. Cyr '942 envisions administering a pentose to increase the energy available to "mammals having a chronic low energy level due to advanced age, trauma, sepsis, or such disease conditions as congestive heart failure and other chronic illnesses" (column 3, lines 43-47 of St. Cyr '942), there is no teaching or suggestion in St. Cyr '942 of actually treating any of the listed conditions (i.e., advanced age, trauma, sepsis, or congestive heart failure) responsible for the chronic low energy level. Notably, as acknowledged by the Examiner, St. Cyr '942 does "not teach administration of antibiotic" (page 6, lines 9-10 of the Office Action mailed May 10, 2011).

St. Cyr '366 "relates to compositions and methods for raising the hypoxic threshold in mammals experiencing a hypoxic condition. Such mammals include humans with cardiovascular

or peripheral vascular disease, or humans undergoing chronic or transient hypoxia" (column 1, lines 11-15 of St. Cyr '366). The Examiner alleged that St. Cyr '366 "teach or suggest administration of ribose to subjects suffering from sepsis" (page 6, lines 8-9 of the Office Action mailed May 10, 2011). Applicants earnestly disagree with the Examiner's allegation, for at least the reason that St. Cyr '366 is ***totally silent regarding mammals having sepsis***. In evaluating lack of disclosure regarding an obviousness rejection, the Court of Customs and Patent Appeals has stated that "[s]ilence in a reference is hardly a proper substitute for an adequate disclosure of facts from which a conclusion of obviousness may justifiably follow." *See*, *In re Burt and Walter*, 148 U.S.P.Q. 548, 553 (C.C.P.A 1966).

Further, although St. Cyr '366 may envision administering ribose to raise the hypoxic threshold in "in mammals with congestive heart failure, coronary artery disease or peripheral vascular disease" (column 2, lines 28-30 of St. Cyr '366), there is no teaching or suggestion in St. Cyr '366 of actually treating any of the listed conditions (i.e., congestive heart failure, coronary artery disease, or peripheral vascular disease) responsible for the hypoxia. Even further, as acknowledged by the Examiner, St. Cyr '366 does "not teach administration of antibiotic" (page 6, lines 9-10 of the Office Action mailed May 10, 2011).

The Examiner urged that Taylor be combined with St. Cyr '366, because "Taylor teaches that tissue hypoxia is likely to occur during sepsis" (page 5, lines 3-4 of the Office Action mailed May 10, 2011). However, Applicants respectfully submit that even if one of skill in the art arguably did have motivation to combine Taylor with St. Cyr '366, one would not arrive at a method for treating sepsis by administering ribose, because St. Cyr '366 teaches the administration of ribose for raising the hypoxic threshold in mammals experiencing a hypoxic condition, not for the treatment of an underlying condition (e.g., arguably sepsis) that may be responsible for the hypoxic condition.

Finally, the Examiner cites Cunha for teaching that "antibiotic therapy is critical to treatment of the septicemic patient" (page 6, lines 11-12 of the Office Action mailed May 10, 2011), and alleged that "[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to carry out the method as discussed above, and to also administer

antibiotic to the subject" (page 6, lines 13-15 of the Office Action mailed May 10, 2011). Applicants disagree for at least the following reasons.

Applicants respectfully submit that Cunha actually teaches away from the administration of other agents with the antiobiotic to treat sepsis. "[A] reference that 'teaches away' from a given combination may negate a motivation to modify the prior art to meet the claimed invention. . . . A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." *Ormco Corp. v. Align Technology Inc.*, 79 U.S.P.Q.2d 1931, 1938 (Fed. Cir. 2006).

Cunha teaches that a single antiobiotic is more than adequate to treat the great majority of septicemic patients ("Monotherapy and fully recommended doses of antimicrobial drugs delivered by the intravenous route as soon as the diagnosis is established remain the cornerstone of therapy in treating the septic patient. Monotherapy with an antibiotic of the appropriate spectrum is more than adequate to treat the great majority of septicemic patients;" lines 6-9 of Cunha abstract). For treatment of specific infections, Cunha teaches that treatment with two antibiotics may be recommended ("Double-drug therapy is recommended to treat febrile leukopenic compromised hosts, serious P. aeruginosa infections, and selected cases of intra-abdominal sepsis;" lines 9-11 of Cunha abstract).

However, Cunha cautions that combining other agents (i.e., corticosteroids and mediator therapy) with antibiotics ***has no place in the treatment of the septic patient*** ("corticosteroids and mediator therapy have no place in the treatment of the septic patient;" lines 11-12 of Cunha abstract). Thus, Applicants respectfully submit that Cunha teaches away from combining other agents (e.g., ribose) with antibiotics to treat sepsis.

For at least these reasons, Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of unpatentability for claims 29-38 being obvious over the combinations of St. Cyr '942, St. Cyr '366, Taylor et al., and Cunha urged by the Examiner. Reconsideration and withdrawal of the rejections under 35 U.S.C. §103(a) are respectfully requested.

Obviousness-Type Double Patenting Rejection

Claims 8 and 21-38 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,218,366 (St. Cyr '366) in view of Taylor et al. (*Am. J. Physiol. Lung Cell Mol. Physiol.*, 1998; *275*:L139-L144) and further in view of Cunha (*Med. Clin. North Am.*, 1995 May; *79*(3):551-558, abstract only). Claims 8 and 21-28 having been canceled, Applicants respectfully traverse this obviousness-type double patenting rejection as applied to claims 29-38 (as amended).

The deficiencies of St. Cyr '366 in view of Taylor et al, and further in view of Cunha as applied to claims 29-38 (as amended) have been discussed herein above with respect to the rejection under 35 U.S.C. §103(a). For similar reasons, Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of unpatentability for obviousness-type double patenting of claims 29-38 (as amended) over claims 1-10 of St. Cyr '366 in view of Taylor et al., and further in view of Cunha. "A double patenting rejection of the obviousness-type . . . is 'analogous to [a failure to meet] the nonobviousness requirement of 35 U.S.C. 103' except that the patent principally underlying the double patenting rejection is not considered prior art." M.P.E.P. §804(II)(B)(1).

Reconsideration and withdrawal of the obviousness-type double patenting rejection are respectfully requested.

Summary

It is respectfully submitted that all the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives at the telephone number listed below if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted
By
Mueting, Raasch & Gebhardt, P.A.
P.O. Box 581336
Minneapolis, MN 55458-1336
Phone: (612) 305-1220
Facsimile: (612) 305-1228
Customer Number 26813

September 12, 2011
Date

By: Matthew W. Adams
Matthew W. Adams
Reg. No. 43,459
Direct Dial 612-305-1227

CERTIFICATE UNDER 37 CFR §1.8:
The undersigned hereby certifies that this paper is being transmitted via the U.S. Patent and Trademark Office electronic filing system in accordance with 37 CFR §1.6(a)(4) to the Patent and Trademark Office addressed to the Commissioner for Patents, Mail Stop Amendment, P.O. Box 1450, Alexandria, VA 22313-1450, on this 12th day of September, 2011.

By: Sue Dombroske
Name: Sue Dombroske